86 / 200 RAT / DERMAL SHEET 1

REPORT ON THE STUDY OF ACUTE DERMAL TOXICITY

ON THE RAT BASED ON OECD *

TESTING FACILITY:	BASF AKTIENGESELLSCHAFT DEPARTMENT OF TOXICOLOGY D-6700 LUDWIGSHAFEN/RHEIN, FRG
AIM OF THE STUDY:	ESTIMATE OF THE POTENTIAL ACUTE HAZARD AFTER 24-HOUR PERCUTANEOUS EXPOSURE (DETERMINATION OF THE LD50)
TEST SUBSTANCE NO.:	86 / 200
NAME OF TEST SUBSTANCE:	2,4,6-TRIANILINO-P-(CARBO-2'-ETHYLHEXYL-1'-OXI)-1,3,5-TRIAZINE **
LOT NUMBER:	18301/142
DEGREE OF PURITY:	98%
PHYSICAL STATE/APPEARANCE:	POWDER, WHITE
HOMOGENEITY:	GUARANTEED BY SHAKING
STORAGE STABILITY AT 8 DEGREE CELSIUS:	ON COMPLETION OF ALL TESTS THE STABILITY OF THE TEST SUBSTANCE WILL BE VERIFIED BY A REPEATED ANALYSIS. THE RESULT CAN BE OBTAINED FROM THE SPONSOR:ME/Z.
STABILITY OF THE TEST SUBSTANCE PREPARATION(S):	CONFIRMED BY ANALYSIS

RESULT

LD50 AFTER 14 D

MA+FE : GREATER THAN 2000 (MG/KG) (1% SIGNIFICANCE LEVEL)

Kirsch Jan. 27, 1987

DR.MED.VET. P. KIRSCH
(HEAD OF SECTION)

Kieczka, Jan. 27, 1987

DR.RER.NAT. H. KIECZKA
(STUDY DIRECTOR)

* METHOD BASED ON OECD GUIDELINE (402) FOR TESTING OF CHEMICALS - ADOPTED MAY 12TH, 1981

** DETAILED INFORMATION ON THE CHARACTERIZATION OF THE TEST SUBSTANCE IS INCLUDED IN THE RAW DATA

THIS REPORT CONSISTS OF 9 PAGES.

ACUTE DERMAL TOXICITY

TEST METHOD:

ANIMAL SPECIES:	RAT/WISTAR/DR. THOMAE
ANIMAL BREEDER:	DR. K. THOMAE GMBH, D-7950 BIBERACH, FRG
ACCLIMATIZATION PERIOD:	ACCLIMATIZATION FOR AT LEAST 1 WEEK
NO. OF ANIMALS PER DOSE:	5 MALE ANIMALS 5 FEMALE ANIMALS
TYPE OF CAGE:	STAINLESS STEEL WIRE MESH CAGES, TYPE DK-III (BECKER & CO., CASTROP-RAUXEL, FRG)
NO. OF ANIMALS PER CAGE:	SINGLE HOUSING
ANIMAL IDENTIFICATION:	IDENTIFICATION OF GROUPS USING CAGE CARDS AND TAIL MARKING
ROOM TEMPERATURE/ RELATIVE HUMIDITY:	THE ANIMALS WERE HOUSED IN FULLY AIR-CONDITIONED ROOMS. CENTRAL AIR-CONDITIONING GUARANTEED A RANGE OF 20 - 24 DEGREES CELSIUS FOR TEMPERATURE AND OF 30 - 70% FOR RELATIVE HUMIDITY. THERE WERE NO DEVIATIONS FROM THESE RANGES WHICH INFLUENCED THE RESULTS OF THE STUDY.
DAY/NIGHT RHYTHM:	12 H/12 H (6.00 - 18.00 HOURS/ 18.00 - 6.00 HOURS)
DRINKING WATER:	TAP WATER AD LIBITUM PER DAY
DRINKING WATER ANALYSIS:	THE DRINKING WATER IS REGULARLY ASSAYED FOR CONTAMINANTS BY THE MUNICIPAL AUTHORITIES OF FRANKENTHAL AND THE TECHNICAL SERVICES OF BASF AKTIENGESELLSCHAFT. IN VIEW OF THE AIM AND DURATION OF THE STUDY THERE ARE NO SPECIAL REQUIREMENTS EXCEEDING THE SPECIFICATIONS OF THE DRINKING WATER.
DIET:	KLIBA-LABORDIAET 343, KLINGENTALMUEHLE AG CH-4303 KAISERAUGST, SWITZERLAND, AD LIBITUM
FEED ANALYSIS:	THE FEED USED IN THE STUDY WAS ASSAYED FOR CONTAMINANTS. IN VIEW OF THE AIM AND DURATION OF THE STUDY THE CONTAMINANTS OCCURING IN COMMERCIAL FEED OUGHT NOT TO INFLUENCE THE RESULTS.
ANIMAL WEIGHTS:	YOUNG ADULT ANIMALS OF COMPARABLE WEIGHT; (+- 20 % OF THE MEAN WEIGHT); RATS 200 - 300 G; FOR WEIGHING DATA SEE SHEET 6.

ACUTE DERMAL TOXICITY

APPLICATION AREA:	ABOUT 50 CM X CM
ROUTE OF APPLICATION:	SINGLE APPLICATION TO THE CLIPPED EPIDERMIS (DORSAL AND DORSOLATERAL PARTS OF THE TRUNK); COVERING OF THE APPLICATION SITE WITH AN SEMIOCCLUSIVE * DRESSING FOR 24 HOURS, AFTERWARD REMOVAL OF THE DRESSING. RINSING OF THE APPLICATION SITE WITH WARM WATER.
TEST SUBSTANCE FORMULATION WITH:	OLIVE OIL
REASON FOR THE VEHICLE:	SOLUBILITY IN OLIVE OIL BETTER THAN IN WATER
FORM OF APPLICATION:	SUSPENSION
REASON FOR THE DOSES:	IN A PRETEST 2000 MG/KG WERE TESTED. NO MORTALITY OCCURED. BASED ON THIS RESULT THE FOLLOWING DOSE HAS BEEN USED IN THE MAIN STUDY: 2000 MG/KG BODY WEIGHT.

AMOUNTS APPLIED:

DOSE (MG/KG)	2000
CONC. (W/V)	25
APPL. VOL. (ML/KG)	8

TIME OF DAY OF APPLICATION:	IN THE MORNING
OBSERVATION PERIOD:	14 D
CLIPPING OF THE FUR:	AT LEAST 15 HOURS BEFORE THE BEGINNING OF THE STUDY
DATE OF APPLICATION:	OCT. 9, 86
SIGNS AND SYMPTOMS:	RECORDING OF SIGNS AND SYMPTOMS SEVERAL TIMES ON THE DAY OF APPLICATION, AT LEAST ONCE EACH WORKDAY. CHECK FOR MORIBUND AND DEAD ANIMALS TWICE EACH WORKDAY AND ONCE ON HOLIDAYS. FOR DATA SEE SHEETS 4 AND 6.
SCORING OF SKIN FINDINGS:	30 - 60 MINUTES AFTER REMOVAL OF THE SEMIOCCLUSIVE DRESSING AND THEN ABOUT ONE WEEK LATER AND BEFORE TERMINATION OF THE STUDY. FOR DATA SEE SHEET 5.
PATHOLOGY:	WITHDRAWAL OF FOOD 16 HOURS BEFORE SACRIFICE WITH CO_2; THEN NECROPSY WITH GROSS-PATHOLOGICAL EXAMINATION. NECROPSY OF ALL ANIMALS THAT DIE AS EARLY AS POSSIBLE.
RETENTION OF RECORDS:	THE RAW DATA AS WELL AS THE ORIGINAL OF THE PROTOCOL AND OF THIS REPORT ARE RETAINED AT BASF AKTIENGESELLSCHAFT AT LEAST FOR THE PERIOD OF TIME SPECIFIED IN THE GLP-REGULATIONS. THE CONDUCT OF THE STUDY IN CONFORMANCE WITH GLP WAS MONITORED BY THE QUALITY ASSURANCE UNIT.
DATA INPUT:	BECHTOLD
DATA CONTROL:	Benz, Nov. 11, 1986

* THE APPLIED TEST SUBSTANCE HAS BEEN COVERED WITH A POROUS DRESSING (FOUR LAYERS ABSORBENT GAUZE AND POROUS BANDAGE).

ACUTE DERMAL TOXICITY

R E S U L T S:

SYMPTOMS MALE ANIMALS:

DOSE (MG/KG)	2000

NO ABNORMALITIES

SYMPTOMS FEMALE ANIMALS:

DOSE (MG/KG)	2000

NO ABNORMALITIES

ACUTE DERMAL TOXICITY

LOCAL FINDINGS MALE ANIMALS:

DOSE (MG/KG)	2000

NO ABNORMALITIES

LOCAL FINDINGS FEMALE ANIMALS:

DOSE (MG/KG)	2000

NO ABNORMALITIES

ACUTE DERMAL TOXICITY

DOSE (MG/KG)	2000

MORTALITY:

MA:	
NO. OF ANIMALS:	5
DEAD ANIMALS AFTER	
1 H	0
1 D	0
2 D	0
7 D	0
14 D	0
FE:	
NO. OF ANIMALS:	5
DEAD ANIMALS AFTER	
1 H	0
1 D	0
2 D	0
7 D	0
14 D	0

MEAN WEIGHT (G):

MA:	
BEG. OF THE TEST:	251
AFTER:	
7 D	278
13 D	308
FE:	
BEG. OF THE TEST:	210
AFTER:	
7 D	234
13 D	252

KEY: W/V = WEIGHT/VOLUME
MA = MALE
FE = FEMALE
D = DAY
H = HOUR
BEG. = BEGINNING

ACUTE DERMAL TOXICITY

LD50 DETERMINATION : OBSERVATION PERIOD 14 D
ANIMALS MALE AND FEMALE

DOSES (MG/KG)	NUMBER OF ANIMALS	DEAD ANIMALS AFTER 14 D	MORTALITY (%)	DOSES USED FOR CALCULATION
2000	10	0	0.0	*

LD50 > 2000 (1% SIGNIFICANCE LEVEL)

ACUTE DERMAL TOXICITY

NECROPSY FINDINGS:

Sacrificed animals (male + female):

Organs: no abnormalities detected.

Nov. 17, 1986

PATHOLOGY

Dr.med.vet. Freisberg

BASF
Toxikologie

STATEMENT

of the quality assurance unit

Number of test substance: 86/200

Name of test substance: 2,4,6-Trianilino-P-(Carbo-2'-Ethylhexyl-1'-Oxi)-1,3,5-Triazine

Type of study: Study of acute dermal toxicity on the rat

The quality assurance unit inspected the study, audited the final report, and reported findings to the study director and to management.

Date of inspection	Report to study director and to management
Oct. 2, 1986	Oct. 9, 1986
Oct. 9, 1986	Oct. 9, 1986
Jan. 27, 1987	Jan. 27, 1987

Ludwigshafen/Rhein, Jan. 29, 1987

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Signature QAU